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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,002	01/25/2001	Peter Lloyd Amlot	4-30583A	5207

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EXAMINER	
EWOLDT, GERALD R	
ART UNIT	PAPER NUMBER
1644	15

DATE MAILED: 09/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/770,002	Amlot et al.
Examiner	**Art Unit**
G.R. Ewoldt	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *4/16/02 and 7/9/02* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-6 and 8-11* is/are pending in the application.

4a) Of the above, claim(s) *1-3, 6, and 9-11* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *4, 5, and 8* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's election of Group II, Claims 4-6 and 8, with traverse, in Paper No. 12, filed 4/16/02, and the species, rheumatoid arthritis, with traverse, in Paper No. 14, filed 7/09/02, is acknowledged. Applicant argues that proper restriction requires that the inventions be both independent and distinct, and that the Examiner has failed to show a serious search burden.

This is not found persuasive for the following reasons. While the inventions of Groups I and II may not be independent, they are distinct as defined by the MPEP § 802.01 as being "patentable over each other". MPEP § 803 further states that independent and distinct is to be considered independent *or* distinct for restriction purposes. Restriction between patentably distinct inventions can be proper even if said inventions are considered dependent, if undue search burden is established. Regarding search burden, the issues and limitations involved in the search of a product are clearly not coextensive with the issues and limitations involved in the search of a method of treatment, thus, search burden has been established.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-3 and 9-11 are withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention. Claim 6 is withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b) as being drawn to a nonelected species.

Claims 4, 5, and 8 are being acted upon.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 4, 5, and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, Claims 4 and 5 depend on nonelected Claim 1.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 4, 5, and 8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

There is insufficient written description to show that Applicant was in possession of a CD25 binding molecule, other than basiliximab. The specification discloses that "By "CD25 binding molecule" is meant any molecule capable of binding to the CD25 antigen either alone or associated with other molecules to form high affinity IL-2 receptors." Said definition must clearly be considered to encompass a large genus that might include peptides, proteins, and mimitopes, etc. However, the specification discloses just a single antibody (basiliximab) capable of binding CD25. Additionally, the specification neither defines nor discloses any "direct equivalents" of CDR1, CDR2, nor CDR3 of the CD25 binding molecule as recited in Claim 1. Accordingly, one of skill in the art must conclude then that the specification fails to disclose a representative number of species to describe the claimed genus. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103 (c)and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 4, 5, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 89/09622 (IDS) in view of Kovarik et al. (1997).

WO 89/09622 teaches a method of treating rheumatoid arthritis comprising administering an effective amount of a CD25 binding molecule. The reference further teaches the coadministration of a further substance effective in the treatment of rheumatoid arthritis (e.g., methotrexate) (see particularly page 12).

The reference differs from the claimed invention in that it does not teach the administration of a CD25 binding molecule comprising a CDR1, CDR2, and CDR3 having the amino acid sequences Arg-Tyr-Trp-Met-His, Ala-Ile-Tyr-Pro-Gly-Asn-Ser-Asp-Thr-Ser-Tyr-Asn-Gln-Lys-Phe-Glu-Gly, and Asp-Tyr-Gly-Tyr-Tyr-Phe-Asp-Phe, respectively, nor direct equivalents.

Kovarik et al. teaches a CD25 binding molecule comprising a CDR1, CDR2, and CDR3 having the amino acid sequences Arg-Tyr-Trp-Met-His, Ala-Ile-Tyr-Pro-Gly-Asn-Ser-Asp-Thr-Ser-Tyr-Asn-Gln-Lys-Phe-Glu-Gly, and Asp-Tyr-Gly-Tyr-Tyr-Phe-Asp-Phe, respectively, (basiliximab) (see particularly page 1702, column 1, *Study treatments*). The reference also teaches that serum concentrations of basiliximab sufficient to saturate IL-2 receptors were achievable (see particularly *Pharmacokinetics*, Tables 1 and 2)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform a method of treating rheumatoid arthritis comprising administering an effective amount of a CD25 binding molecule, with or without coadministration of a further substance effective in the treatment of rheumatoid arthritis, as taught by WO 89/09622, employing basiliximab, as taught by Kovarik et al. One of ordinary skill in the art at the time the invention was made would have been motivated to use basiliximab as the CD25 binding

agent because basiliximab was a well-known CD25 binding agent and it was known that serum concentrations of basiliximab sufficient to saturate IL-2 receptors were achievable, as taught by Kovarik et al. Note that the saturation of IL-2 receptors is the mechanism by which the treatment of the instant claims would be expected to functions.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
September 5, 2002